STATE OF MICHIGAN
DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY
LANSING

GRETCHEN WHITMER
GOVERNOR

DANIEL EICHINGER
ACTING DIRECTOR

March 13, 2023

VIA E-MAIL and U.S. MAIL

Jim Saric
Remedial Project Manager
United States Environmental Protection Agency
Region 5
77 West Jackson Boulevard (S-6J)
Chicago, Illinois 60604-3511

Dear Jim Saric:

SUBJECT: Michigan Department of Environment, Great Lakes, and Energy (EGLE) comments on the Area 5 Supplemental Remedial Investigation (SRI) Report, Revision 2 (Report), dated January 16, 2023, Operable Unit 5 (OU5), Allied Paper Inc./Portage Creek/Kalamazoo River Superfund Site (Site).

By way of this correspondence, EGLE formally submits this cover letter and detailed comments (attached) on the subject SRI Report for inclusion in the Administrative Record for the Site.

EGLE appreciates the opportunity to review and comment on the subject Report for OU5. If you have any questions, please contact Daniel Peabody, Environmental Quality Analyst, Remediation and Redevelopment Division at 517-285-3924; PeabodyD@Michigan.gov; or EGLE, P.O, Box 30426, Lansing, Michigan 48909-7926

Sincerely,

Daniel A. Peabody

Daniel Peabody
Environmental Quality Analyst
Superfund Section
Remediation and Redevelopment Division

att/cc:

Greg Baker, National Oceanic and Atmospheric Administration
Lisa Williams, United States Fish and Wildlife Service
Dr. Keegan Roberts, CDM Smith
Matt Diana, MDNR
Brian Gunderman, MDNR
Mark Mills, MDNR
David Kline, EGLE
Joseph Walczak, EGLE

## GENERAL COMMENTS

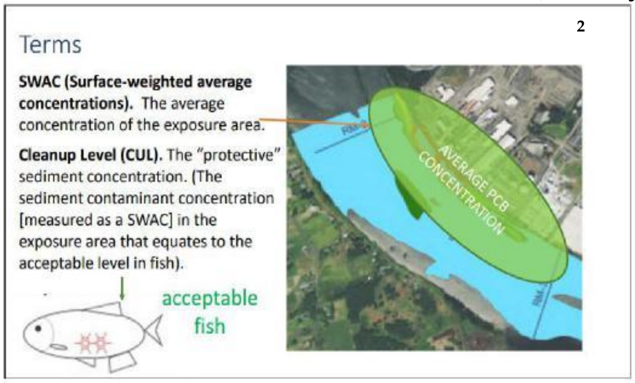
**Commenting Organization: EGLE**
**General Comment #1:** As shown in Figure ES-2 and Figure 1-2 and described in the Supplemental Remedial Investigation (SRI) Report, Revision 2 (SRI Report), the 9.1 miles of river channel in Area 5 was divided into four Sections based on large-scale geomorphology (the Impounded Lake and the Channelized Flow Reach that is made up of 3 river sections [Sections 1, 2, and 3)]). Some basic information on the four Sections is provided below:

- The Impounded Lake is formed by the Allegan City Dam and is the most downstream investigative reach. The Impounded Lake begins at the downstream boundary of Area 5 (the Allegan City Dam) and extends approximately 1.35 miles upstream. The Impounded Lake is 111 acres in size, and it contains thick accumulations of fine-grained sediments.
- The Channelized Flow Reach covers the remainder of Area 5 (approximately 7.75 miles.). In general, the Channelized Flow Reach has thinner deposits of sediment than the Impound Lake. The Channelized Flow Reach is divided into three Sections (Section 1, 2, and 3).
    - Section 1 begins at the upstream boundary of Area 5 (the Trowbridge dam) and extends downstream approximately 1.6 miles.
    - Section 2 begins at the downstream boundary of Section 1 and extends approximately 3.3 miles downstream.
    - Section 3 begins at the downstream of Section 2 and extends downstream approximately 2.75 miles and ends at the upstream boundary of the impounded lake.

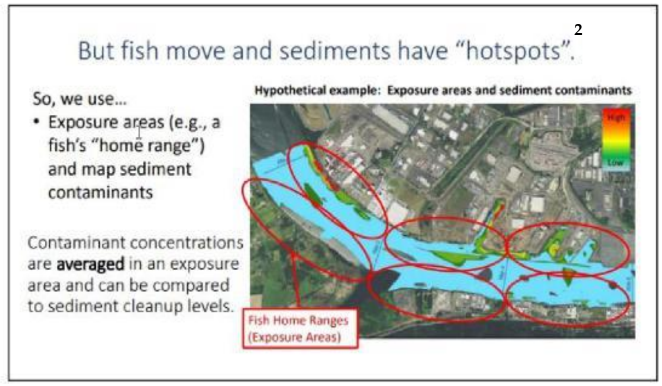
Summary statistics and surface area-weighted average concentrations (SWACs) for total PCBs were calculated for each Section by sample interval and are presented in Table 4-2, Table 4-3, Table 4-4, and Table 4-5 of the SRI Report. The summary statistics and SWACs developed for each Section and sample interval are compared to relevant clean-up levels (CULs) for sediments (0.33 milligram per kilogram [mg/kg]) in the SRI Report text, and details on the process for developing sediment SWACs are located in Appendix T of the SRI Report.

Sediment SWAC calculation areas may be based upon human or ecological exposure areas, the home ranges of fish and/or other aquatic species, as well as differences in the river's flow rate, bottom profile or slope, velocity, or other distinct geomorphic reaches of the river[1]. Sediment CULs derived from fish tissue contaminant levels assume a fish exposure area, and we use that exposure area (e.g., a fish's "home range") to map contaminants and produce average concentrations over an exposure area that can be compared to CULs[2] at a spatial scale that is relevant to the exposure pathway and receptor[3].

If SWACs are to be used as an exposure and protectiveness metric, then it is critical that they are appropriately derived and sized for the associated exposure pathway and receptor so that CULs are achieved over a relevant spatial scale(s)[4]. If SWACs are applied to areas much larger than discrete source or a receptors' exposure areas, then a SWAC analysis may not delineate a footprint appropriate for targeting sources or reducing exposure[5], and high concentration areas can be "averaged out" but still drive bioaccumulation and risk[3].



[2]



[2]

The SRI Report does not propose remedial action objectives (RAOs) for Area 5 and states that RAOs will be developed as part of the Alternatives Screening Technical Memorandum and Feasibility Study. However, EGLE anticipates that the RAOs developed for Area 5 will generally be consistent with RAOs that have been proposed and established for other Areas (e.g., Area 1, Area 2, Area 3, and Area 4). Two RAOs that have been developed for other Areas utilize resident fish (adult and young-of-year smallmouth bass [SMB]) as the receptor, and both RAOs are achieved through removal of contaminated sediments and attainment of the 0.33 ppm CUL for total PCBs upon completion of the remedial action.

No site-specific studies have been conducted to look at movement of SMB within the Superfund site and a "home range" has not been considered or developed, but information on a potential "home range" for SMB is available in the scientific literature. SMB tracking studies conducted in riverine systems, including one study conducted on a river located in central Michigan that is very similar to the Kalamazoo River, have generally noted that SMB movements in these systems are fairly restricted - on the order of tens to hundreds of meters for juvenile and adult SMB - and observed that SMB may respect stream features (i.e., riffles or pools) as boundaries[6,7].

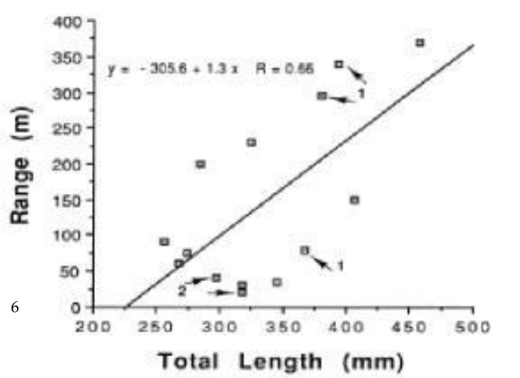
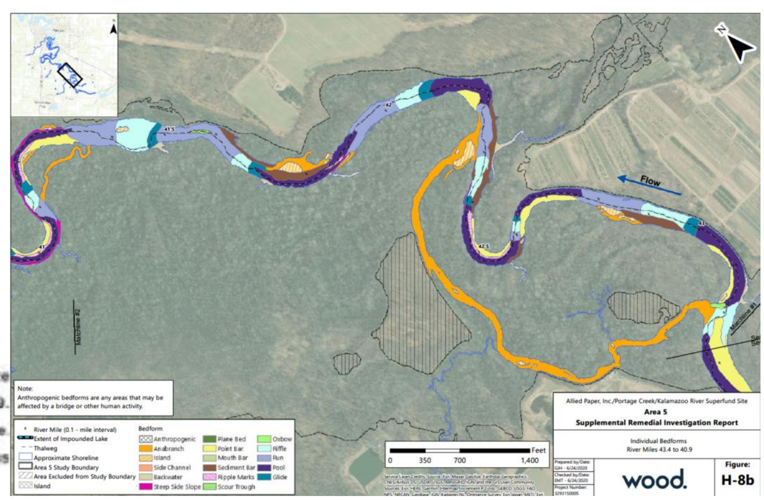
[6]



Figure 4. The relationship between total length and total range size for smallmouth bass tracked between May 1988 and November 1989. Each point represents either a spring/summer or fall/winter range. Two fish (1 and 2) were tracked for longer than one season; lengths were estimated for a typical growing season.

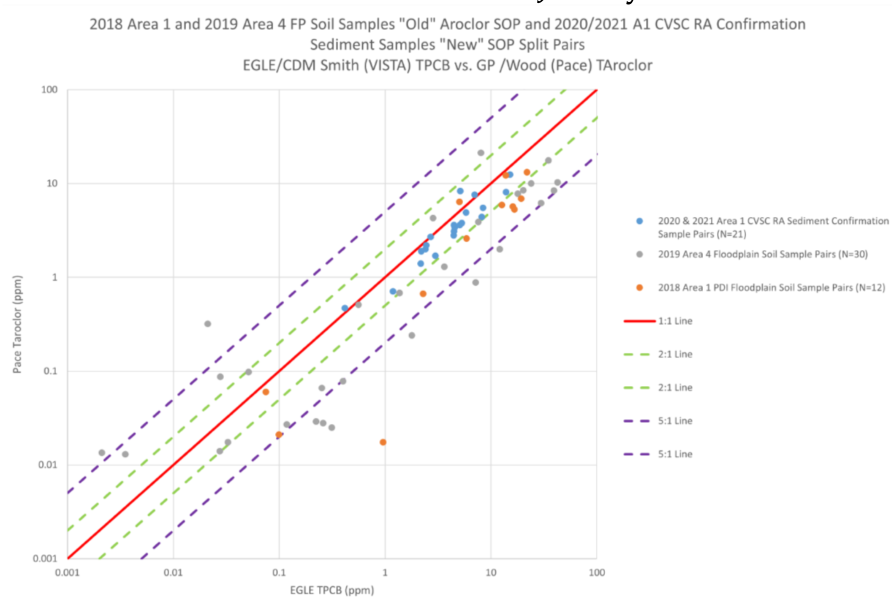


An example of the bedform mapping that was completed for Area 5 and is presented in the SRI Report (and detailed in Appendix H) is inserted above. The example figure provided shows key stream features (bedforms) of interest (e.g., riffles, pools, etc.) over a portion of Section 2. The bedform mapping that was completed for Area 5 shows that the bedform geometries and the distance from pool-to-pool and riffle-to-riffle are variable, but pool-pool and riffle-riffle sequences generally repeat every 300 meters (0.2 miles) to 500 meters (0.3 miles) in the Channelized Flow Reach. Figures in Appendix H suggest that there are a total of nine riffle-riffle sequences over 3.3 miles in Section 2 and ten riffle-riffle sequences over 2.75 miles in Section 3.

Sediment SWACs for total PCBs in the SRI Report are calculated for each Section by sample interval, and Sections range from 1.35 miles to 3.3 miles in length. Based on the observed movements of SMB in riverine systems similar to the Kalamazoo River and the site-specific geomorphology of Area 5, the exposure area that is represented by the calculated SWAC and used for comparison to the sediment CUL of 0.33 mg/kg for total PCBs in the SRI Report is likely significantly larger than a SMB "home range". As a result, the general approach for developing SWACs in the SRI Report, which is based on large-scale geomorphology, may not be sufficient to identify sources or reduce receptor exposure. Sediment SWAC calculations should be developed over a smaller distance (area) that more closely replicates a potential exposure for the species of interest (SMB), which is likely on the order of a few hundred meters. Those results should be presented alongside the sediment SWACs for total PCBs that were developed for each Section based on large-scale geomorphology. Revise the document accordingly.

**Commenting Organization: EGLE**
**General Comment #2:** Prior to conducting the Phase 2 SRI, EGLE communicated concern that there may be a low bias in total PCB concentrations reported by Georgia-Pacific's (GP's) laboratory. EGLE suspected there may be a substantial and systemic low bias in GP's Aroclor results after splits of samples collected by GP and provided to EGLE during the Area 1 Pre-Design Investigation (PDI) showed a significant low bias when GP's total PCBs via the Aroclor method (Method 8082) to EGLE's total PCB via the congener method. In 2019, an investigation in Area 4 completed by the EPA and GP definitively concluded that GP's total PCB measurements are biased low and significant adjustments to the analytical methodology was necessary. Following the Area 4 sampling, the US EPA spent extensive resources and involved regional and national technical experts to evaluate and compare analytical methodologies amongst labs and attempt to standardized laboratory procedures. The result of this painstaking effort was the development of a site-specific standard operating procedure (SOP) for laboratories that use Method 8082 for analysis of sediments and soils.

An insignificant problem wouldn't have warranted such a significant effort, and we are grateful for the time that was devoted to this issue. As shown in the 1-1 plot below, the adoption of the site-specific SOP for M8082 has markedly improved the quality of data being generated by GP's lab and it is clear that data collected before and after implementation of the SOP are different. The plot shows that the measured Aroclor result for the parent sample analyzed by GP's lab under the "new" SOP is still generally less than the measured total PCB concentration for the split sample analyzed by EGLE's lab, however; the magnitude of the bias in samples analyzed using the "new" SOP is significantly less than the magnitude of the bias in samples analyzed using the "old" SOP.




Going forward there is a need to ensure that data collected under the site-specific SOP is accurate over time and space, and across laboratories. There is also a need to figure out how to handle and integrate data that is biased low with other datasets. If total PCB measurements are inaccurate and biased low the nature and extent of contamination and perceived risks in Area 5 may be underrepresented and remedial footprints may be artificially reduced.

The SRI Report should be updated to include a discussion on how the low bias in total PCB concentrations in the Area 5 Phase 1 and Phase 2 SRI data is being accounted for.

**Commenting Organization: EGLE**
**General Comment #3:** EGLE continues to have significant concerns about the updates to the Area 4 Terrestrial Baseline Ecological Risk Assessment (TBERA) that were made and used to calculate risk-based concentrations (RBCs) for dioxins (total TEQ) that are supposed to be protective of mammals and birds, and that TBERA is now being recycled and utilized as part of the SRI Report. RBCs for total TEQ developed for birds and mammals as part of the Area 4 SRI Report are now pending preliminary remediation goals (PRGs) for Area 4. EGLE's technical concerns with the Area 4 TBERA show that the PRGs selected for PCBs and dioxins were not scientifically defensible and will not be protective. All those comments are now applied to the Area 5 TBERA. Additional information previously provided by EGLE on the Area 4 TBERA is attached.

The SRI Report states that the pending avian PRG for Total TEQs is 7,000 ng/kg. EGLE has previously noted concerns regarding the Total TEQ PRG for avian ecological receptors of 7,000 ng/kg, since the avian TRVs (NOAEL=14 ng TEQ/kg/day and LOAEL=140 ng TEQ/kg/day) derived from Nosek et al. (1992) are acute lethality values. Section 5.2.2 of the November 16, 2018, TBERA (Appendix L of the Area 4 SRI) states, *"Mortality was observed in birds exposed at a concentration of 140 ng/kg/day, with 57 percent of the birds in this group dying between weeks 15 and 24…Greater than 98 percent embryo mortality was observed in eggs laid by hens exposed at a concentration of 140 ng/kg/day. Based on the observed mortality, reduced egg production, and lower embryo survival at an exposure dose of 140 ng/kg/day, a LOAEL TRV of 140 ng/kg/day and a NOAEL of 14 ng/kg/day were* *identified from this study."* Consequently, a cleanup based on the LOAEL value will potentially result in mortality of half of the resident invertivorous birds, and nearly complete mortality of their eggs. Substituting NOAELs for LOAELs in EPA's method, EGLE estimates the protective avian PRG in this scenario to be 375 ng/kg Total TEQ. Note, avian Total TEQs in the surface soil range from 6.7 to 764 ng/kg and from ND to 2,646 ng/kg in Interval 2 soil, exceeding EGLE's estimated avian PRG. EGLE strongly encourages EPA to reassess the pending avian PRG for Total TEQ.

**Commenting Organization: EGLE**
**General Comment #4:** Site decision making is predicated on the assumption that addressing risk to total PCBs will adequately address risks to secondary constituents of concern (COCs), including dioxins (total TEQ). Samples collected from residential properties during the remedial design PDI in Area 1 and analyzed for total PCBs and dioxins show that in some instances total TEQ (not total PCBs) may drive risk. The degree of co-location between total PCBs and total TEQ in Area 5 has not been thoroughly evaluated, and dioxin data across OU5 is sparse. As such, we are in a unique position of not being able to describe total TEQ distribution with the same clarity that we can describe total PCB distribution. However, as previously mentioned, there is also low bias in the total PCB results that were collected to support the Area 5 SRI. If total PCB measurements in the SRI samples are inaccurate and biased low, the PCB remedial footprints may no longer be sufficient to address risk to dioxins. Any future sampling plans in Area 5 must cover all COCs, including PCBs and dioxins.

**SPECIFIC COMMENTS**

**Commenting Organization: EGLE**
**Section: 4.4 Surface Water** **Page #: 4-18**
**Specific Comment #1:** The last sentence of the first paragraph on page 4-18 states, *"Surface water data collected in 2019, 2020, and 2021 are not used in trending for the reasons described below."*

These data should be incorporated into the trending analyses to demonstrate the spike in concentration and the eventual downward trend. The figures showing the 2019 to 2021 data but not including them in the analyses should be replicated with the 2019 to 2021 data included in the analyses. Revise the document accordingly.

**Commenting Organization: EGLE**
**Section: 4.4 Surface Water** **Page #: 4-18**
**Specific Comment #2:** Text in the middle of page 4-18 states, *"The 2019 surface water samples were analyzed via a low-level PCB method in association with the HyST/OPTICS field event (Surface Water Work Plan [SWWP] data). These data from 2019 are not used in temporal trending discussed in Section 4.4.4 because of the difference in sample volume and analytical methods."*

The SWWP and Quality Assurance Project Plan (QAPP) addendum that were submitted provide details on the "low-level PCB method" (the Delaware TMDL method). Specifically, the SWWP and QAPP discuss that the lower detection and reporting limits associated with the Delaware TMDL method will provide a better comparison to screening levels and that by increasing the sample size (volume) and changing the extraction method the method will be able to achieve cleaner background levels and less matrix interference. The data collected as part of programs aimed at evaluating natural recovery were not meant to replace or be completed outside of existing LTM program activities and they were supposed to utilize and supplement the existing baseline LTM dataset that goes back to the 1990s.

While differences in the analytical method may result in some variability in the total PCB result, sample data should not be wholly discounted based solely on analytical methodology. And, the significant shift that is observed when comparing from 2019 data to pre-2019 data highlights the tremendous amount of uncertainty in total PCB concentrations in surface water and our understanding of long-term trends. This type of uncertainty should be discussed in the document rather than dismissing the 2019 results as "unrepresentative" due to changes in the analytical technique, which were specifically implemented with the expectation that data quality would improve.

Data collected in 2019 under the SWWP and as part of various monitoring programs that have been implemented to evaluate natural recovery utilize and are meant to supplement the existing baseline LTM dataset. However, the SRI Report states that these data are not comparable to each other. If the surface water sampling results from 2019 are "different" than pre-and post-2019 data such that they are not usable for trending how does that impact the results and conclusions from data collected as part of the OPTICS study (or other studies) which is dependent on these data? Have surface water sampling protocols for total PCBs changed while the OPTICS program has been ongoing (i.e., from the Delaware TMDL method back to the "standard" method?).

**Commenting Organization: EGLE**
**Section: 6.1.11 Consumption of Wild Game** **Page #: 6-11 to 6-12**
**Specific Comment #3:** Text in Section 6.1.11 identifies several site-specific inputs that are not available to calculate a risk to hunters that consume wild game. The last paragraph of Section 6.1.11 on page 6-12 states, *"Without site-specific data, exposure cannot be quantitatively evaluated with a reasonable degree of accuracy for a variety of hunter scenarios. However, based on RME assumptions from the literature, it is not anticipated that there would be elevated levels of risk from the consumption of wild game by hunters".* The potential risk to hunters that consume wild game has been a long-standing data gap at the site that has not been adequately evaluated, but the potential for unacceptable risk to hunters that consume game has already been documented. Delete the last sentence.

**Commenting Organization: EGLE**
**Section: 6.1 Human Health Evaluation** **Page #: 6-1**
**Specific Comment #4:** Tables indicate that fish consumption cancer risk for both subsistence and sport fisher appear significantly lower than was reported in the 2003 BHHRA (still greater than EGLE acceptable, but lower than 2003). Have the fish tissue concentrations dropped significantly? Section 7 lists some statements about tissue concentration differences over the years, but it adds no support for those statements. The Response to Comments provided by GP for Revision 1 of the Area 5 SRI Report identifies some potential differences in how the risks to anglers are calculated in the SRI Report and the Human Health Risk Assessment, but no discussion was inserted in the text of the SRI Report describing these differences. Revise the document.

**Commenting Organization: EGLE**
**Section: 6.1.12.1 Uncertainties and Assumptions** **Page #: 6-12 to 6-13**
**Specific Comment #5:** A few comments on the Section:

Text in Section 6.1.12.1 states, *"A fish population study was conducted throughout OU5 in 2014 (Amec Foster Wheeler 2015a) which indicated that a 100% SMB diet for subsistence and high-end sports anglers may not be sustainable based on currently available legal-size SMB (minimum of 14 inches long). Therefore, the ingestion rate of subsistence and high-end sports anglers who eat only SMB is conservative."* Add a discussion of equal length about the potential for anglers to take and consume fish that do not meet the legal-size requirements. A subsistence angler would be opportunistic by nature, and it would not be reasonable to assume that a subsistence angler eats only SMB. Revise the document accordingly.

Text at the bottom of page 6-12 and continuing on the page 6-13 states, *"Cancer incidence age-adjusted rates for Kalamazoo and Allegan Counties, respectively, are 476.1 per 100,000 and 393.28 per 100,000. The statewide age-adjusted rate is 477.70 per 100,000. These data are for years 2008–2012 (MDHHS 2016). Thus, the Kalamazoo County rate is almost the same as the statewide rate, while the Allegan County rate is lower than the statewide rate. These statistics may suggest that exposure to PCBs through fish ingestion has not observably increased the incidence of cancer in Kalamazoo or Allegan Counties."* No recent studies examining the incidence of cancer associated with anglers that consume fish from the Kalamazoo River have been conducted. Delete these sentences.

References

1. Contaminated Sediment Technical Advisory Group (CSTAG) Memorandum: "CSTAG Recommendations on the Lower Passaic River Study Area, 17 Mile Remedial Investigation/Feasibility Study and Proposed Interim Remedial Action". April 25, 2018. (https://semspub.epa.gov/work/02/534001.pdf)
2. Remediation Goals for the Fish Tissue Exposure Pathway at Contaminated Sediment Sites: Policy & Practice. Karl Gustavson. January 5, 2022. (https://clu-in.org/conf/tio/ralcl_010622/slides/1Slide_Presentation_for_Karl_Gustavson,_Ph.D.;_U.S._EPA.pdf)
3. W. David Keefer, Chief, Region 4, correspondence to Karl Gustavson, Chair, CSTAG, "CSTAG Recommendations on Operable Unit 4, Anniston PCB Site". November 25, 2020.
4. Karl Gustavson, Chair, CSTAG, correspondence to Pamela Scully, EPA Region 4 Remedial Project Manager, "Memorandum: CSTAG Recommendation on Operable Unit 4, Anniston PCB Site. CSTAG milestone Meeting 2 and 3". November 25, 2020. (https://semspub.epa.gov/work/04/11167477.pdf)
5. Michael Sivak, Chief, EPA Region 2 correspondence with Karl Gustavson, Chair, CSTAG, "CSTAG Memorandum Recommendations on Operable Unit 4, the Lower Passaic River Study Area, 17 Mile Remedial Investigation/Feasibility Study, Interim Remedial Action - Draft Feasibility Study and Overall Cleanup Strategy". March 2, 2020. (https://semspub.epa.gov/work/02/615443.pdf)
6. Jennifer D. Beam. Daily and Seasonal Movement, as Related to Habitat Use, of Smallmouth bass in the Huron River, Michigan. July 6, 1990.
7. Brown, T.G., Runciman, B., Pollard, S., Grant, A.D.A., and Bradford, M.J. 2009. Biological Synopsis of Smallmouth Bass (Micropterus dolomieu).

Attachment 1 – EGLE Comments on the Area 4 TBERA

# Area 4 – TRV/RBC Comments

Supporting Information

## Summary – MDEQ Evaluation of Area 4 RBCs from Revised SRI

- Both avian and mammalian RBCs are appropriate for risk management
- Consideration of bioaccumulation (exposure duration and tissue half-life of xCDD) is critical to both development and use of RBCs
- RBCs based on earthworm BAFs (fox, shrew, woodcock, and robin) need to be recalculated using appropriate BAF data (not just two Sonford samples)
- The avian LOAEL (Nosek et al.) is actually a dose that would result in 100% mortality. Accounting for bioaccumulation significantly lowers the RBCs for the woodcock, robin, and wren
- The mammalian LOAEL (Sparschu et al.) is overestimated because it does not consider bioaccumulation. RBCs are again significantly overestimated
- Accounting for bioaccumulation is an overarching concern that applies regardless of any other uncertainties identified in the SRI Appendix L and in MDEQ comments on the document

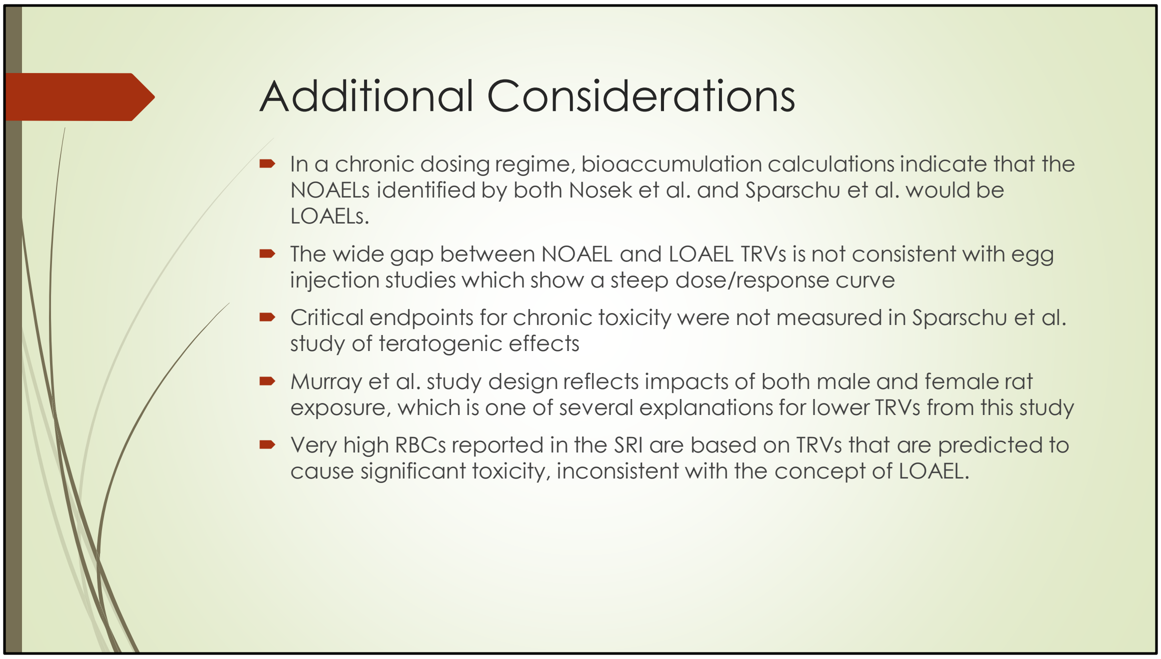
1. Wood/GP have stated that the avian RBCs were not appropriate because of uncertainty in the TEFs. However, the avian TEFs were selected from appropriate studies that were evaluated by a World Health Organization panel of international experts and found to be suitable for use as avian TEFs. The derivation of avian RBCs is equally as valid as the derivation of mammalian RBCs.

2. Wood/GP used short-term studies to derive TRVs. When assessing bioaccumulative contaminants, it is critical to utilize studies that include steady-state tissue concentrations. A dose that may not impact a mammal after a 10-day exposure may kill that same animal after 90-days.

3. Earthworm BAFs are both the foundation of, and the risk drivers for, the derivation of RBCs. The earthworm BAFs used by Wood/GP are orders of magnitude too low because they were derived through a very complex set of mathematical manipulations performed on only two soil samples from the Sonford, MS site (Sonford data was put through normalization/denormalization/renormalization for soil TOC and tissue lipids, along with weighting/deweighting/reweighting TEFs based on the mixtures of D/Fs). The current RBCs (and the potential remediation) are wholly based on two

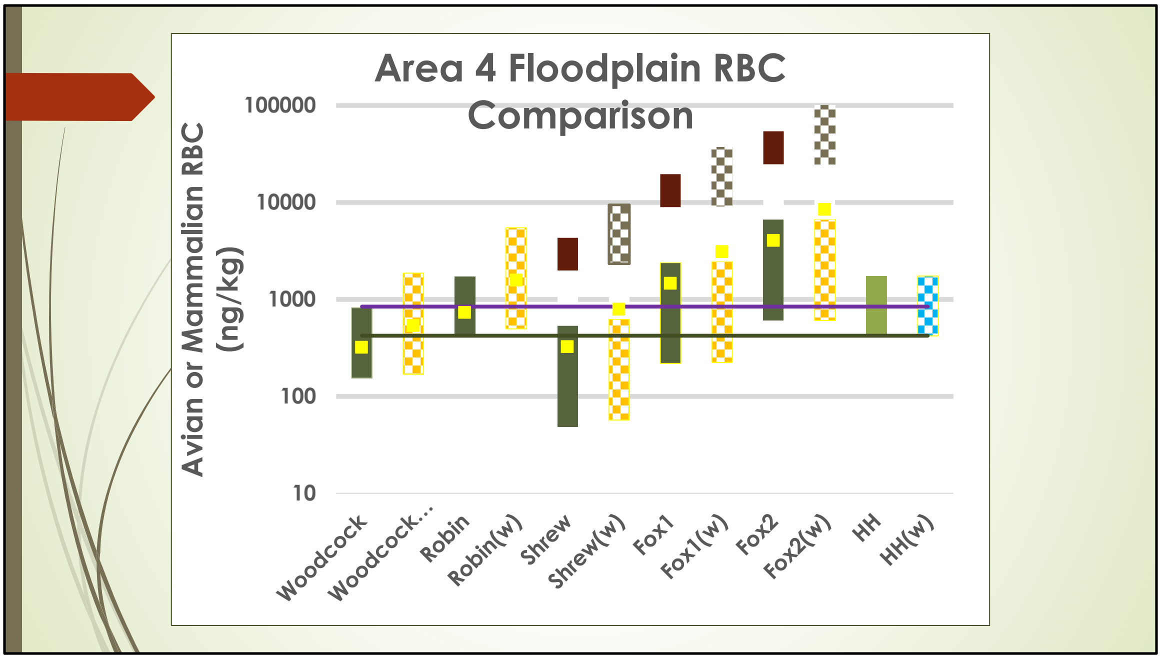
soil samples from a site in another state. This approach is unacceptable.

4. MDEQ has evaluated Wood/GP's bases for TRVs for both avian and mammalian receptors and has determined that RBCs derived from these TRVs are not protective. The following slides summarize this evaluation, and slide notes also cross reference Excel spreadsheets that provide details of the approaches and input parameters for all calculations. The Excel spreadsheets are active to provide transparency.




1. “LOAELs” from Nosek et al. (14 ng/kg-d) and Sparschu et al. (30 ng/kg-d) are in an exposure range where adverse effects are anticipated. However, Wood/GP used the Nosek et al. value as a NOAEL in their derivation of RBCs. The Sparschu et al. value is an exposure concentration that would result in significant adverse effects after a chronic exposure. Since significant toxicity was observed at the higher short-term exposuress, these LOAELs will significantly overestimate and yield RBCs that are not protective.

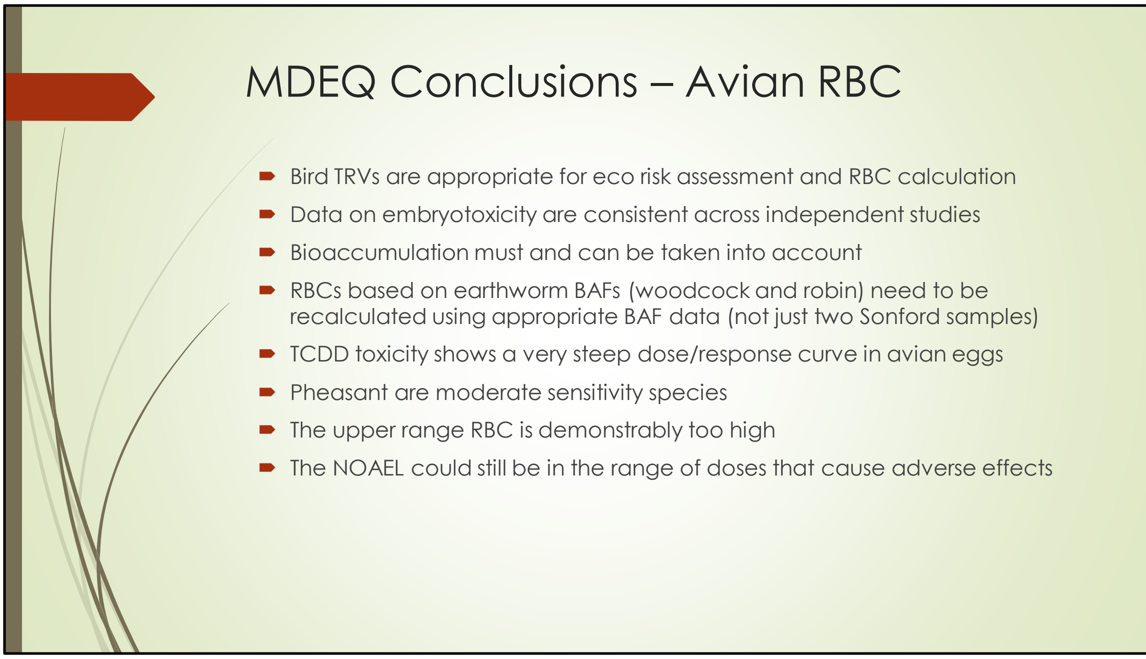
2. MDEQ stresses the importance of using the Murray et al. TRV values because the three-generation study with continuous feeding exposure of both male and female rats clearly shows that longer-term exposure (as will happen in the Kalamazoo floodplain) shows that accumulation of these bioaccumulative compounds yields toxic impacts at concentrations orders of magnitude lower than the values derived from the Sparschu et al. 10-day, short-term exposure of already-pregnant rats. These facts indicate that the NOAELs used by Wood/GP are likely to still produce adverse impacts.




1. This chart is an overall summary of the analysis that compares RBCs calculated by Wood/GP without consideration of bioaccumulation (checkered bars) to revised RBCs calculated by CDMS/MDEQ taking into account impacts of bioaccumulation on TRV estimates (solid bars). The data and calculations are provided in the accompanying Excel file titled: "Revised_Area4_Floodplain_RBC_Summary_060418".
2. The yellow squares are the geometric means across the RBC estimates (NOAEL and LOAEL based (ecological risk). Geometric means were not calculated for the HH RBCs.
3. The (w) following receptors on the x-axis indicate that values in the chart are from Wood/GP.
4. Each bar for ecological receptors represents NOAEL and LOAEL estimates from a single TRV source. For example, the bottom of the solid **ocher bar** for the woodcock is the NOAEL and the upper end is the LOAEL derived from TRVs from Nosek et al. as developed by CDMS/MDEQ using bioaccumulation. The checkered **ocher bar** for woodcock(w) is similar, but is developed from Nosek et al. by Wood/GP without consideration of bioaccumulation.
5. For mammals (shrew and fox) the **ocher bars** represent TRVs from Murray et al., and the **dark blue** bars represent TRVs from Sparschu et al. For the fox, the

dietary assumptions of both soil to bird (fox1) and insect to bird (fox2) are presented. Again, solid bars represent TRVs adjusted for bioaccumulation.

6. The solid horizontal lines represent 420 ppt, the RBC estimate based on a cancer risk for recreational visitors of 1 in 100,000, and 840 ppt, a midpoint of values based on cancer and non-cancer endpoints. Calculations of RBC used spreadsheets provided by Wood/GP with the only modification being revised TRVs (see following slides).

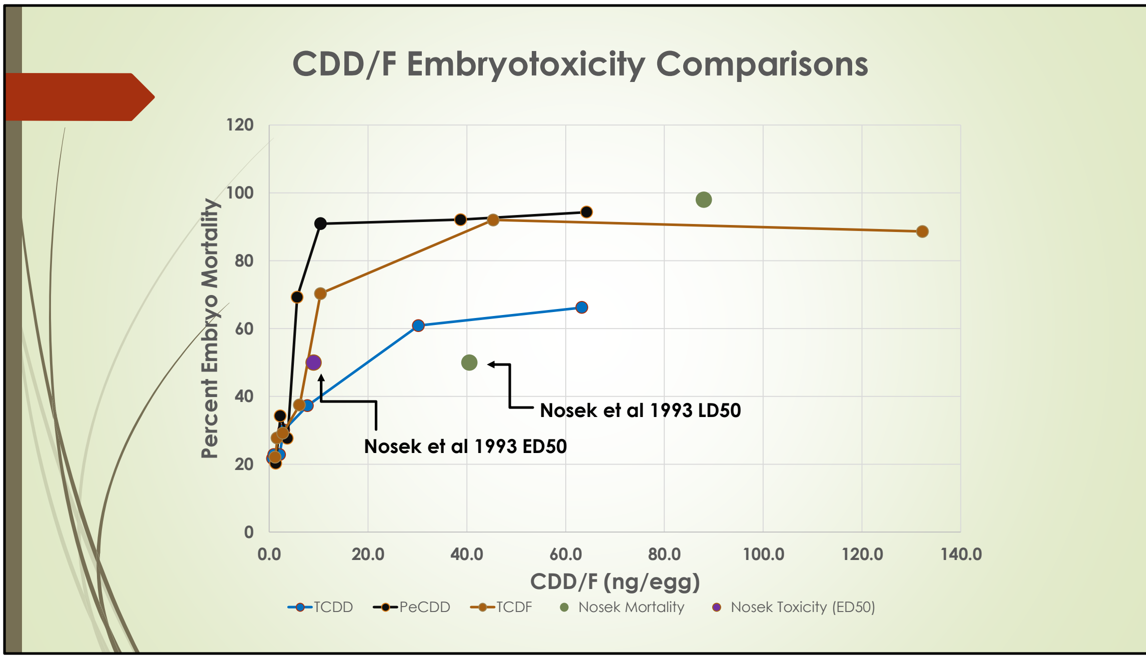



1. Details of the analysis of avian TRV are provided in the following slides.

2. Data and calculations for all of the analysis are provided in the accompanying Excel file titled: “Embryotoxicity_Cohen-Barnhouse_053118”.

3. Note that BAFs were not altered in the calculations of RBCs, and, as already shown, the earthworm BAFs are not appropriate.

4. Additional discussion will be needed to determine appropriate BAFs for uptake of xCDD/F into earthworms.

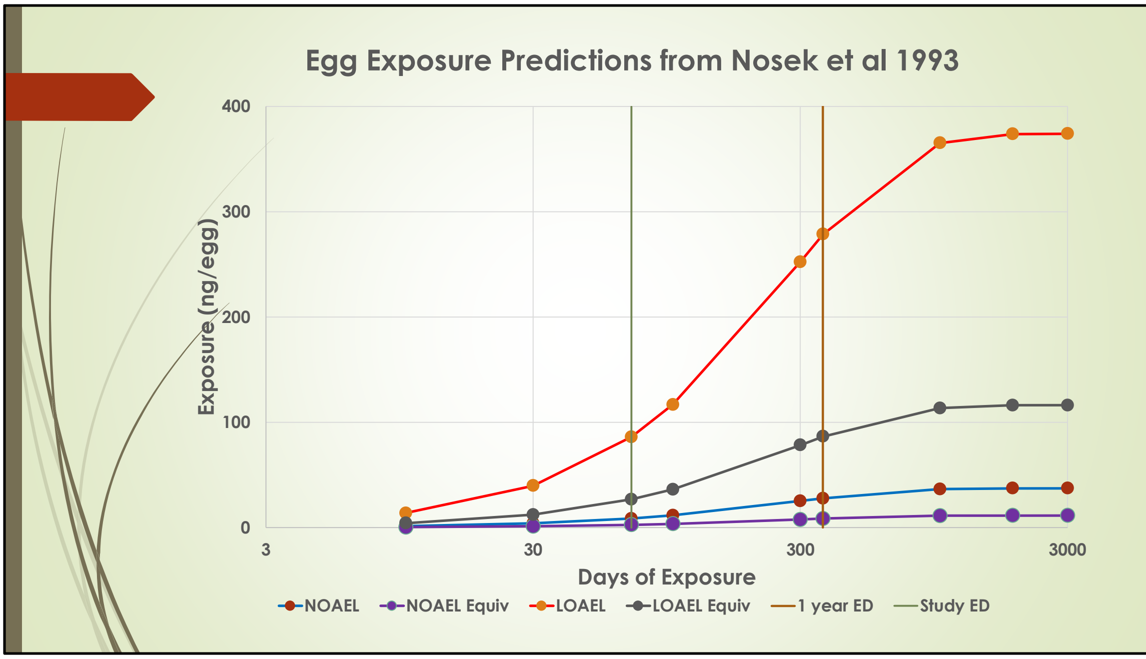



1. This figure uses literature data to demonstrate the steep dose response curve for egg injection studies. The data and calculations are provided in the accompanying Excel file titled: "Embryotoxicity_Cohen-Barnhouse_060418".

2. For PeCDD, control to 100% mortality occurs over a range of 0 to 10 ng/egg.

3. An $LD_{20}$ (a non-conservative endpoint to use to quantify a lethality LOAEL) would be in the range of 2 ng/egg (control mortality was about 20 percent so that an increase of 20% would occur at about 3 ng/egg).

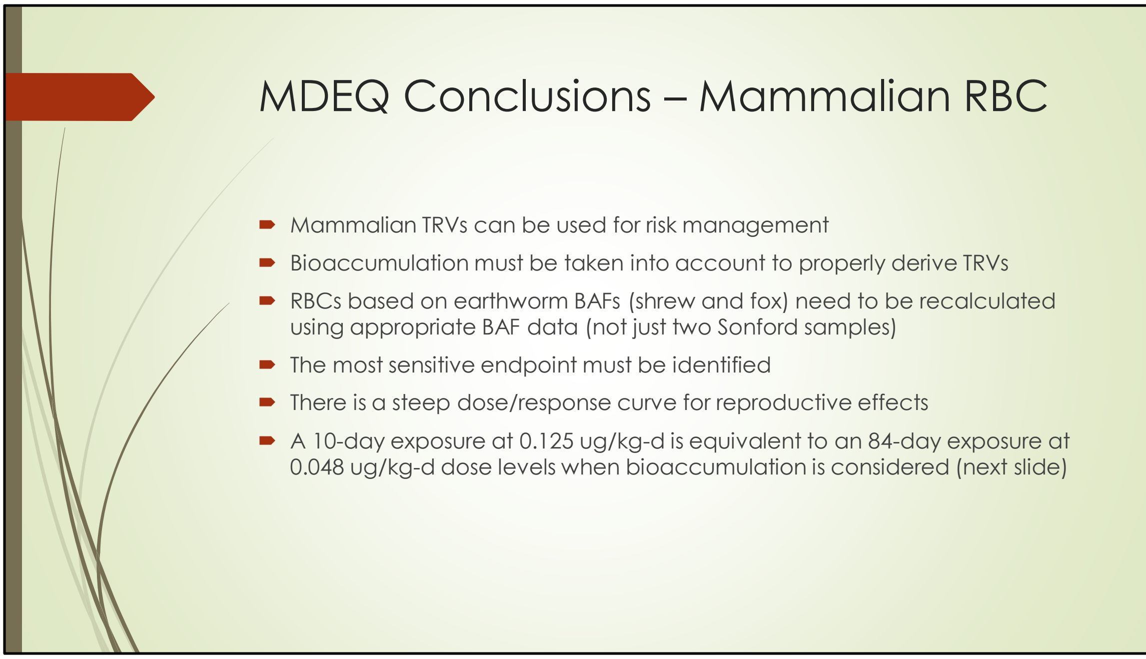
4. The egg injection study results compare well with results of hen dosing reported by Nosek et al. The $ED_{50}$ for hen toxicity occurs at a slightly higher dose than does embryo mortality. Further, any $LD_{50}$ for embryo mortality is consistent with almost complete mortality in egg injection studies. Exposure rate for hens that result in a dose to eggs in the range of a few ng/egg are likely to result in significant impacts.




1. This chart plots predicted body burdens for hens at exposure rates used in the Nosek et al. study. Data and calculations are provided in the accompanying Excel file titled: "Embryotoxicity_Cohen-Barnhouse_060418".
2. Body burden is used as a surrogate for plasma concentrations since the volume of distribution of xCDD in pheasants is not known. Nosek et al. reported impacts to embryos in terms of percent body burden transferred to egg yolk. At a rate of 140 ng/kg-d for 70 days, body burden calculations suggest a dose of nearly 100 ng/egg.
3. For the same exposure duration, a dose rate of 14 ng/kg-d is predicted to be within the lower range of doses that may cause adverse effects.
4. The Study ED line shows the point in time where investigators ceased dosing.
5. Predicted body burden is much higher if exposure (140 ng/kg-d) is assumed to continue to for a year (one year is used because pheasants are not expected to lay until the next year's breeding season). Doses of close to 300 ng/egg are anticipated under this scenario.
6. The study NOAEL dose rate (14 ng/kg-d) suggests impacts in the range of 20 ng/egg. To recalculate a RBC based on body burden, an exposure rate that results in a similar estimate of ng/egg after 365 days of exposure (as was reported by Nosek et al. after 70 days of exposure) was estimated. This dose rate (43 ng/kg-d)

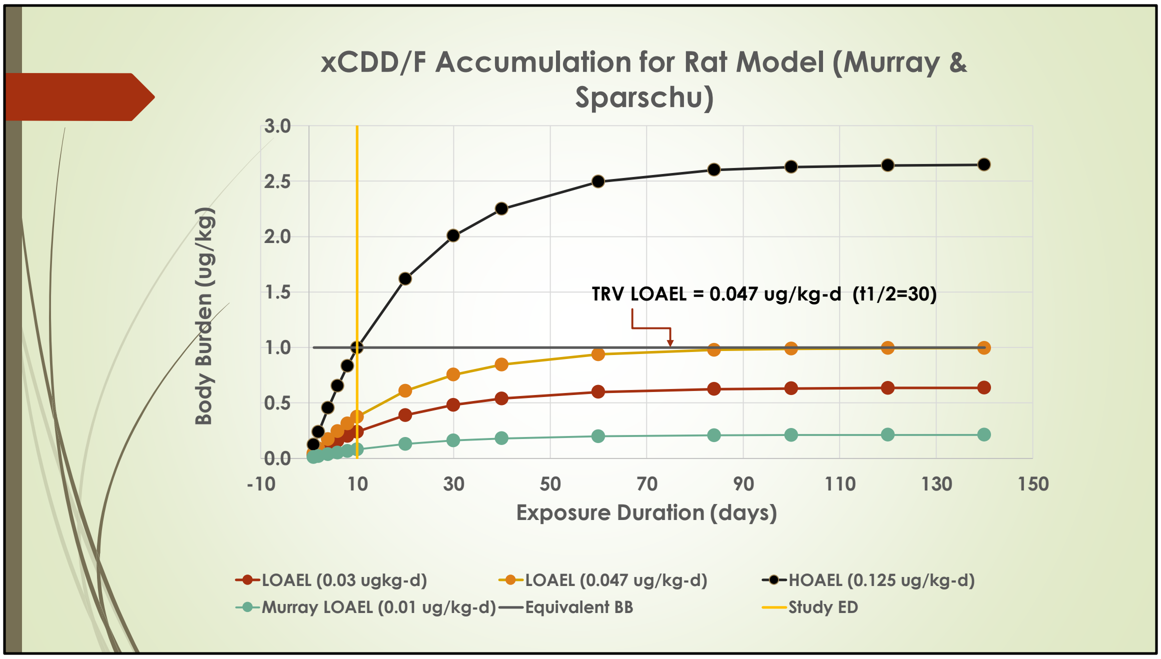
is recommended as a upper range estimate of LOAEL (i.e., a dose rate that is likely to result in significant toxicity).

7. A dose rate for a one-year exposure duration that predicts the same body burden as estimated for a 70 day exposure is 4.3 ng/kg-d, which is only 31 percent of the NOAEL generated by the Nosek et al. study. This 4.3 ng/kg-d dose rate is recommended as a NOAEL for chronic exposure.
8. Note that estimates for ng/egg for both NOAEL and LOAEL may fall above the range of doses that cause toxicity in injection studies.




1. Details of the analysis of mammalian TRV are provided in the next slides. Data and calculations for all of the analysis are provided in the accompanying Excel file titled: “xCDD_Accumulation_Rat_Predictions_060418”.

2. Note that the BAFs were not altered in the calculations of RBCs, and, as already shown, the earthworm BAFs are not appropriate.  Additional discussion will be needed to determine appropriate BAF for uptake of xCDD/F into earthworms.




1. This chart plots predicted body burdens for rats at exposure rates used in the Murray et al. and Sparschu et al. studies. Data and calculations for all of the analysis are provided in the accompanying Excel file titled: "xCDD_Accumulation_Rat_Predictions_060418".
2. Body burden is used as a surrogate for plasma concentrations since volume of distribution of xCDD in rats is not known.
3. Calculations assume a half-life for xCDD of 30 days. This assumption is reasonable for lower chlorinated congeners, but likely underestimates half-life for congeners with higher levels of chlorination.
4. Sparschu et al. reported impacts after 10 days of exposure of embryos at a dose rates of 0.125 ug/kg-d and higher. Toxicity was not observed at a dose rate of 0.03 ug/kg-d over the same time period. The short exposure duration does not allow for bioaccumulation and significantly underestimates body burden after longer exposure periods.
5. The Study ED line shows point in time where investigators ceased dosing.
6. Predicted body burden is much higher if exposure is assumed to continue for several half-lives. To recalculate a RBC based on body burden, an exposure rate was estimated that results in a body burden after 100 days of exposure that is similar to the body burden predicted at 10 days. This dose rate (0.047 ng/kg-d) is

recommended as a upper range estimate of LOAEL (i.e., a dose rate that is likely to result in significant toxicity).

7. Similarly, a dose rate of 0.011ug/kg-d for a 100 day exposure duration predicts the same body burden as estimated for a 10 day exposure, which is essentially the same as the LOAEL estimated in the Murray et al. study.
8. Recommendations for mammalian TRVs are therefore: NOAEL = 0.001 ug/kg-d (Murray et al.); LOAEL = 0.01 ug/kg-d (Murray et al. and Sparschu et al.); LOAEL (upper range estimate) = 0.047 ug/kg-d (Sparschu et al.).

## Summary

### Preliminary Revised TBERA RBCs using results of bioaccumulation calculations

(subject to change with revised earthworm BAF)

| | Woodcock | Robin | Shrew | Fox1 | Fox2 | HH |
|---|---|---|---|---|---|---|
| **NOAEL** | 154 | 416 | 48 | 218 | 605 | |
| **LOAEL** | 665 | 1286 | 483 | 2177 | 6050 | |
| **LOAEL (upper)** | | | 1449 | 6531 | 18149 | |
| **Rec HH CSF** | | | | | | 420 |
| **Rec HH Rfd** | | | | | | 1320 |
| **Geomean** | 320 | 731 | 323 | 1457 | 4050 | NA |

All units in ng/kg TCDD equivalents in soil

1. Revised RBCs are designated “preliminary”, because revisions to the earthworm BAFs are required before any avian or mammalian RBC can be calculated.
2. The corrected earthworm BAF will significantly affect the RBCs for woodcock, robin, shrew, and fox, the species most at risk for adverse effects of TCDD equivalents in soil.

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| | | | | The RBCs for Kalamazoo were derived using site-specific data and inputs. However, the RBCs were based on TRVs that were not appropriate. The RBCs derived for the Tittabawassee River were also derived using site-specific data and inputs, but they are in line with estimates from the scientific literature. The EPA established risk management principles to make scientifically sound and nationally consistent risk management decisions at Superfund sediment sites. The RBCs for the Kalamazoo River floodplain are not expected to be identical to those from the Tittabawassee River floodplain, but they are expected to be consistent and in the same approximate range. |
| 69. | L4-2 | Appendix L, Section 4.2 | Depth intervals | The inconsistency between depth intervals for tPCB and the smaller data set for tPCB, DLC TEQ, and D/F TEQ is not supported. Applying surface (0 to 12”) results to estimate DLC and D/F TEQ to the deeper interval (12” to 24”) may not be appropriate since timeframes for deposition in former impoundment sediments presumably vary with depth, and for D/F, no data are available for this interval. The solution proposed in the TBERA is to examine tPCB and DLC TEQ over a 0 to 24-inch interval and D/F TEQ over a 0 to 12 inch interval. Since, as stated in the text, tPCB concentrations decrease with depth, this approach may underestimate exposure to receptors, particularly for birds for which DLC are particularly important and will also decrease in concentration with depth. A parallel set of calculations using a 0 to 12 inch interval should be included to demonstrate the impact of the approach using disparate depth intervals for PCB/DLC and for D/F TEQ. Include the calculations and revise the text, tables, and figures accordingly. |
| 70. | L4-7 and L4-11 | Appendix L, Sections 4.4.2 and 4.5.3 | For the PCB (PCB and DLC TEQ) evaluation, the available house-wren egg PCB data collected by MSU and floodplain soil PCB data collected by BBL in the former Trowbridge Impoundment were considered in developing the BAF for estimating egg tissue concentrations. | House wren diet composition indicates that they are the least susceptible to exposure to tTEQ in soil. As insectivores, their exposure is largely or wholly absent of soil and earthworm intake, which are primary sources of exposure to other avian receptors. The TBERA must indicate that risks and RBCs for this species, and others in the same guild, cannot be weighted equally with risks and RBCs derived for vermivorous species. |
| 71. | L5.2 and L5.2.2 | L5-2 and L5.4 | “PCB 105 and 118, two of the dioxin-like PCB congeners studied, induced AHR-mediated effects in ringnecked pheasant (Phasianus colchicus) (a moderate sensitivity species (emphasis added)) and | These conflicting statements must be reconciled. In general, available evidence does not suggest any ability to determine sensitivity based on systematic relationships. Cite evidence that pheasant is a moderately sensitive species (e.g. Nosek et al. 1993, “We conclude that embryo mortality is the most sensitive sign of TCDD toxicity in the ring-necked pheasant following in ovo exposure. The ring-necked pheasant embryo is less sensitive than the chicken (*Gallus domesticus*) embryo and more sensitive than the eastern bluebird (*Sialia sialis*) embryo to TCDD toxicity. Farmahin et al. 2013, Ile324_Ala380 and Val324_Ser380 genotypes confer intermediate sensitivity to DLCs in birds. We compared ligand-induced transactivation |

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| | | | Japanese quail (Coturnix japonica) (a low sensitivity species) at levels equivalent to or greater than chickens (a highly sensitive species)."<br><br>and<br><br>"In addition, the ring-necked pheasant is a gallinaceous bird, which is generally considered to have greater sensitivity to DLC exposures than other avian species based on molecular characteristics of the ligand binding domain (Powell et al. 1996a and 1997; Brunström and Reutergardh, 1986; Brunström 1988; Seston 2009)." | function of full-length AHR1s from chicken, common tern, ring-necked pheasant (*Phasianus colchicus*; Ile324_Ala380) and Japanese quail (*Coturnix japonica*; Val324_Ala380); Head and Kennedy 2009, chicken and pheasant EC50 and LD50 differ by an order of magnitude with chicken being the more sensitive species. Turkey and quail are also gallinaceous species and are two orders of magnitude less sensitive than chicken). Remove unjustified/unsupported speculation in Section 5.2.2. |
| 72. | L5-5 and L5-9, etc. | Appendix L, Sections 5.2.2, 5.3.2, 5.3.3, 6.1, 6.3.1, 6.4.4, 6.4.5, 6.5.1, 6.5.2, 7<br><br>Table 5-2 | Page L5-5: "As mortality is the most sensitive response to D/F by pheasants (Elliot et al., 1996), it is likely to provide conservative results for assessing risk to other avian species."<br><br>Page L5-9: "Because the Murray et al. (1979) reproductive endpoints are over an order of magnitude lower than reproductive effect levels observed in all the other studies reviewed, use of this NOAEL TRV selected for mammals may overstate toxicity because it is not bounded by other studies and is an artifact of the doses selected for testing (i.e., 1 and 10 ng/kg BW/day)." | The quoted statement regarding Elliot et al. 1996 is difficult to reconcile with a LOAEL that is greater than the $LD_{50}$. Over half of the birds in the studies died after dosing. This statement is also inconsistent with the complaint later in the report that implies that the order of magnitude dose range in the Murray et al. study creates an "artifact" in TRVs. The "LOAEL" derived from the Nosek et al. study is based on an extreme dose that is highly likely to mask less dramatic, but still quite adverse effects that would occur at lower levels of exposure. The suggestion that because the endpoint of the study is mortality, the "LOAEL" will be protective is entirely incorrect. Sub-lethal adverse effects will occur at lower levels of exposure and the Nosek study does not derive a LOAEL that is useful in determining a protective RBC. That is, with soil concentrations at the LOAEL, both high and mid-sensitivity avian receptors would be eliminated (killed); information in the study is insufficient to determine where, in the interval between the NOAEL and the extreme LOAEL, an appropriate LOAEL might fall. An appropriate toxicological assessment of LOAEL-based RBCs must be included to acknowledge the substantial uncertainty in them as "protective" and "conservative" levels. The Nosek study is not appropriate for establishing protective soil concentrations, and LOAEL-based RBC must be considered non-protective for chronic reproductive and developmental impacts.<br><br>Additionally, during the 5/8/18 in-person meeting between EPA, AMEC/GP, and MDEQ in Kalamazoo, MDEQ detailed the necessity for including bioaccumulation and depuration half-life in the selection of TRVs for bioaccumulative compounds such as D/F and PCBs. MDEQ's 6/11/18 email to AMEC/GP and EPA (Peabody to Draper, Fogell, and Dillon, subject: Area 4 WG Meeting Presentation) included the PowerPoint presentation (along with complete notes for each presentation slide) and three Excel spreadsheets with all step-by-step calculations to demonstrate that using short-term studies such as the Nosek study will yield RBCs that are not protective. |
| 73. | L5-10, etc. | Appendix L, Sections 5.2.2, 5.3.2, 5.3.3, 6.1, 6.3.1, 6.4.4, 6.4.5, 6.5.1, 6.5.2, 7<br><br>Table 5-2 | First full paragraph | The document contains erroneous, scientifically unsupported statements in Appendix L concerning toxicological studies (e.g, Murray) that need to be removed from the document and replaced as specified in below and in subsequent comments.<br><br>The citation (Sparschu et al. 1971) used for derivation of one set of mammalian TRVs is only a 10-day acute study. EPA guidance indicates that chronic studies should be used when available as a basis for evaluation of remedial alternatives. RBCs calculated based on TRVs from this study are, predictably, orders of magnitude higher that RBCs for any other receptor and will not be protective for avian or small mammalian receptors. Appropriate caveats concerning this study, along with an unbiased acknowledgement of multiple studies in the literature that show TRVs well below (e.g. more than an order of magnitude lower) than TRVs derived from Sparschu et al. and that fall in and below the range of TRVs derived from the study by Murray et al that continues to form the basis for EPA evaluation of ecological risks for mammalian receptors. The Murray et al. study was used as the source of TRVs for the Tittabawassee River ecological work. Such discussion must be included everywhere in the TBERA where used as the source of TRVs for the Tittabawassee River ecological work. Such discussion must be included everywhere in the TBERA where TRVs are discussed. Section identified for revision are included in column 3. See also additional specific comments on Appendix L below |

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| | | | | The TBERA states that the TRVs developed using Murray et al. (1979) yielded endpoints ten times lower than other studies, and that it may overstate toxicity. However, the TBERA does not account for the fact that the Murray study was a long-term multigeneration study and was therefore significantly more sensitive and representative than the other shorter studies reviewed. Additionally, as demonstrated during the 5/8/18 in-person meeting between EPA, AMEC/GP, and MDEQ in Kalamazoo, MDEQ detailed the necessity for including bioaccumulation and depuration half-life in the selection of TRVs for bioaccumulative compounds such as D/F and PCBs. MDEQ's 6/11/18 email to AMEC/GP and EPA (Peabody to Draper, Fogell, and Dillon, subject: Area 4 WG Meeting Presentation) included the PowerPoint presentation (along with complete notes for each presentation slide) and three Excel spreadsheets with all step-by-step calculations to demonstrate that using long-term studies such as the Murray study will yield RBCs that include the effects of bioaccumulation and are protective. Moreover, as discussed below, several chronic exposure studies did, in fact, indicate TRVs at and even below the TRVs developed from the Murray et al. study.<br><br>A 10-day study, by Sparschu et al. (1971) assessing teratogenic effects in partial-term fetuses cannot be used assess to the sustainability of small mammal populations, nor can it be used to assess the impacts of bioaccumulation. The focus on teratogenicity resulted in a short gavage exposure of adult (136 days old) pregnant rats for only 10 days (from days 6 to 15 of gestation), and limited outcomes were used to assess toxicity. No males were exposed to 2,3,7,8-TCDD, so there is no inclusion of impacts to sperm which have been demonstrated at the concentrations tested in the Murray study (Latchoumycandane and Mathur 2002). The mothers were decapitated at gestation Day 20 to assess the fetuses. While the study was an assessment of sub-lethal effects, it was not a chronic study, it did not include male exposure, and it did not include gestation to full-term. Clearly, the Sparschu study does not support RBC that are protective for any receptor addressed in the TBERA and, thus, for any additional species represented by these receptors.<br><br>Sparschu did report significant toxicity (e.g., fetal resorptions) starting at a dose (0.125 ug/kg-d) similar to the dose reported by Murray (0.1ug/kg-d). Sparschu did not, however, examine other endpoints, such as fertility, litter size, gestational survival, post-natal survival, post-natal body weight, all of which were reported by Murray at lower doses in the second and third generations. Those long-term effects resulted from bioaccumulation of 2,3,7,8-TCDD. The Sparschu study was by design, incapable of observing chronic toxicity that occurs at the lowest effective doses.<br><br>Finally, the dosing regimens for the Sparschu and Murray studies were quite different – once daily doses administered via gavage during the middle 10 days of the normally 22-day gestation period versus continuous daily doses in food starting 90-days prior to pregnancy and continuing for three generations. Cumulative impacts of continuous exposure to TCDD could only be observed the Murray study. Additionally, the Murray study notes that pharmacokinetic studies have indicated that 2,3,7,8-TCDD approaches steady-concentrations in the body in 90 days (Murray cites Rose et al. 1976). The Murray study exposed both male and female rats from 7 weeks old (approximately 49 days) for 90 days prior to mating and continued to feed TCDD-dosed food to the mothers and offspring for the duration of the three-generation study. The TCDD body burden had likely reached steady-state before the rats were impregnated. The results of the Murray paper are representative of long-term exposure of mammals to 2,3,7,8-TCDD.<br><br>Endpoints assessed by Sparschu are important for describing some aspects of short-term TCDD toxicity, but they are not endpoints that delimit LOAELs or NOAELs. The three generation, reproductive animal study of Murray is notably more powerful. Following EPA's 1997 ERAGS (EPA 540-R-97-006), the Sparschu study must not be given much if any weight in selecting RBCs for tTEQ for use in alternatives analysis. This ERA guidance states that that reproduction, growth, and survival are the key endpoints for consideration (Section 2.5 Assessment & Measurement Endpoints), and while teratogenicity is a viable endpoint, it accounts for only a fraction of possible effects on successful reproduction. Finally, hierarchy of preference is given for chronic effects (e.g., lifetime, multigenerational) over sub-chronic (less than lifetime) effects, over acute, short-term effects (Exposure Duration, Section 1.3.1 Preferred Toxicity Data). Sparschu falls into the realm of short-term and would typically not be used for setting chronic TRVs. With all its deficits for developing appropriate TRVs for TCDD, the Sparschu study does not meet criteria for establishing either chronic LOAELs or NOAELs for TCDD. In other comments, MDEQ indicates that this EPA document is labeled "do not cite or quote" and should be |

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| | | | | removed. The table below is included simply to show that evidence was available from multiple studies to inform the TBERA on the range of NOAEL/LOAEL values in the literature. The EPA report in question should be removed from TBERA along with any quotation(s). |

Latchoumycandane, C. and Mathur, P. Effects of vitamin E on reactive oxygen species-mediated 2,3,7,8-tetrachlorodibenzo-p-dioxin toxicity in rat testis, *Journal of Applied Toxicology*, 22, pg. 345-351, 2002.

Murray, et al., Three generation reproduction study off rats given 2,3,7,8- Tetrachlorodibenzo-p-dioxin (TCDD) in the diet, *Toxicology and Applied Pharmacology*, Vol. 50 (2), pgs. 241-252, 1979.

Rose, J.Q., J.C. Ramsey, T.H. Wentzler, R.A. Hummel, and P.J. Gehring. 1976. The fate of 2,3,7,8-tetrachlorodibenzo-p-dioxin following single and repeated oral doses to the rat. *Toxicol. Appl. Pharmacol.* 36, 209-226.

Sparschu, et al., Study of the teratogenicity of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in the rat, *Food and Cosmetic Tox.* 9(3), pg., 405-412, 1971.

EPA. 1997. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final, EPA 540-R-97-006, 1997.

For reference, all of the following LOAEL/LOEL values were taken from an EPA report ***referenced in the TBERA*** (EPA. 2010. *EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* EPA/600/R-10/038A). Clearly, LOAELs (and NOAELs found in the same report) are consistent with Murray et al., particularly for chronic studies for reproductive endpoints. In other comments, MDEQ indicates that this EPA document is labeled "do not cite or quote" and should be removed. The table below is included simply to show that evidence was available from multiple studies to inform the TBERA on the range of NOAEL/LOAEL values in the literature. The EPA report in question should be removed from TBERA along with any quotation(s).

## Summary of Available Studies for Mammalian TRVs

**LOAELs less than those developed using Sparschu et al. and in the range of those developed using Murray et al.**

**Reproductive Endpoints**

| Study | Year | Species | TRV | Type | Comment |
|---|---|---|---|---|---|
| Franc et al. | 2000 | Rat | 30 | LOAEL | Increased liver weight, decreased thymus weight |
| Hochstein et al. | 2001 | Mink | 2.65 | LOAEL | Reduced kit survival. Mink and Shrew in Same Order in Class Mammalia |
| Hutt et al. | 2008 | Rat | 50 | LOAEL | Only one dose used in study. Fewer normal pre-implantation embryos |
| Ikeda et al. | 2005 | Rat | 16.5 | LOAEL | Decreased ventral prostate development, altered sex ratio (fewer males) |
| Latchoumycandane and Mathur | 2002 | Rat | 1 | LOAEL | Reduced sperm production, decreased reproductive organ weights |
| Murray et al. | 1979 | Rat | 10 | LOAEL | Decreases in fertility, number of live pups, gestational survival, |

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| | | | | | postnatal survival and postnatal body weight |
| Shi et al. | 2007 | Rat | 0.71 | LOAEL | Decreased estradiol levels |
| Yang et al. | 2000 | Rhesus Monkey | 17.86 | LOAEL | Increases in endometriosis and implant diameters, and cytokine dysregulation |
| | | | | | |
| **Developmental Endpoints** | | | | | |
| Bell et al. | 2007 | Rat | 2.4 | LOAEL | Delayed BPS |
| Franczak et al. | 2006 | Rat | 7.14 | LOAEL | Decreased serum estradiol |
| Hojo et al. | 2002 | Rat | 20 | LOAEL | Abrogation of sexually dimorphic neurobehavioral responses |
| Kattainen et al. | 2001 | Rat | 30 | LOAEL | Impaired tooth development |
| Keller et al. | 2007 | Mouse | 10 | LOAEL | Studies conducted with three strains of mice |
| | | Mouse | 10 | LOAEL | Studies conducted with three strains of mice |
| | | Mouse | 10 | LOAEL | Reduced number of serotonin-immune reactive neurons |
| Kuchiiwa et al. | 2002 | Mouse | 0.7 | LOEL | |
| Li et al. | 2006 | Mouse | 2 | LOAEL | |
| Markowski et al. | 2001 | Rat | 20 | LOAEL | Lowest dose administered, single acute |
| Miettinen et al. | 2006 | Rat | 30 | LOAEL | Lowest dose administered, dental caries |
| Ohsako et al. | 2001 | Rat | 50 | LOAEL | Reduced anogenital distance |
| | | | | | |
| **Chronic (noncancer)** | | | | | |
| Cantoni et al. | 1986 | Rat | 1.43 | LOAEL | Increased coproporphyrin excretion |
| Hassoun et al. | 2002 | Rat | 2.14 | LOEL | Increase superoxide anion, lipid peroxidation, DNA SSBs in liver/brain |
| Maronpot et al. | 1993 | Rat | 35.7 | LOAEL | Increased liver weight and lesions |
| NTP | 1982 | Rat/Mouse | 1.4 | LOAEL | Liver lesions (mice) |
| NTP | 2006 | Rat | 2.14 | LOAEL | Increased liver weight, hepatocellular hypertrophy, alveolar/bronchiolar epithelial metaplasia |
| Sewall et al | 1993 | Rat | 3.5 | LOEL | Decreased EgFR $B_{max}$ levels |
| Sewall et al. | 1995 | Rat | 35 | LOAEL | Decreased T4 |
| Toth et al. | 1979 | Mouse | 1 | LOAEL | Skin lesions, amyloidosis (lethal) |
| Vanden Heuvel et al. | 1994 | Rat | 1 | LOEL | CYP1A1 induction |
| | | | | | |

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| 74. | L5-8 to L5-10, etc. | Appendix L, Sections 5.2.2, 5.3.2, 5.3.3, 6.1, 6.3.1, 6.4.4, 6.4.5, 6.5.1, 6.5.2, 7<br><br>Table 5-2 | Inaccuracies and citation errors in both sections | The TBERA adds a secondary set of dietary D/F TEQ TRVs, after stating that the Murray et al (1979) TRVs are too low. The Sparschu et al (1971) study is introduced, and the TBERA states that the Sparschu study had a similar ranking score to the Murray study. While the Sparschu study has some value for determining acute exposure risks, it provides no information relevant to developing TRVs based on chronic exposure.<br><br>In a 2004 ecological risk assessment for the Tittabawassee River floodplain assessing D/F risks, only the Murray study was found appropriate and used to develop TEQ TRV RBCs for the shrew and the red fox (Galbraith Environmental Services LLC, Prepared for MDEQ, 2004) as well as Hazard Indices (HI). Under section, 4.2.2 Insectivorous and Carnivorous Mammals (2004 Assessment) the analysis below is provided. |

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| | | | | Sample et al. (1996) reviewed the laboratory studies in which mammals were dosed with PCDD/PCDFs. Only one study subjected a mammal (the laboratory rat) to contaminant over an extended period and quantified the effects on reproduction: Murray et al. (1979) subjected three generations of rats to three dose levels of 2,3,7,8-TCDD. Reproductive LOAELs and NOAELs were 0.00001 and 0.000001 mg/kg bw/d, respectively. From these results, Sample et al. (1996) derived red fox and short-tailed shrew LOAELs (normalized to body weight) of 0.0000053 and 0.000022 mg/kg bw/d, respectively, and NOAELs of 0.0000005 and 0.0000022 mg/kg bw/d, respectively. Poiger et al. (1989, reviewed in Sample et al., 1996) dosed laboratory rats with 1,2,3,7,8-PeCDF, 2,3,4,7,8- PeCDF, 1,2,3,4,8-PeCDF, and 1,2,3,6,7,8-HxCDF over a 13-week time period. However, these studies did not focus on effects on reproduction and are, therefore, not used to select TRVs in this ERA.<br><br>Sample, B.E., D.M. Opresko, and G.W. Suter. 1996. Toxicological benchmarks for wildlife: 1996 revision. Department of Energy, Oak Ridge, TN.<br><br>The discussion of mammalian studies presented in sections 5.3.2 and 5.3.3 is inaccurate, biased, and incomplete. These and other areas of the document discussing mammalian studies will require revision. The Murray et al (1979) three-generation rat study, evaluated by EPA in three separate documents, has generally considered the lowest dose (1.0 ng/kg) to be a NOAEL, although it was acknowledged that potential adverse effects could have occurred at that lowest dose (EPA 1985, 1987, 1995).<br><br>In discussing the Murray study, the SRI included arguments taken directly from "*Do Not Quote or Cite*" EPA documents that were never finalized and were originally based upon the opinion of one scientist (Kimmel 1988; EPA 2010). In accordance with EPA policies, the 1988 and 2010 EPA citations of these drafts will need to be removed from the SRI document.<br><br>The SRI includes factually erroneous conclusions (e.g., Section 5.3.3, 3rd paragraph), shown below, that must be removed from all locations in the document before approval.<br><br>*"Because the Murray et al. (1979) reproductive endpoints are over an order of magnitude lower than reproductive effect levels observed in all the other studies reviewed, use of this NOAEL TRV selected for mammals may overstate toxicity because it is not bounded by other studies and is an artifact of the doses selected for testing (i.e., 1 and 10 ng/kg BW/day). The actual NOAEL could be much higher than the value selected. In addition, given the fact that the NOAEL TRV is more than an order of magnitude below the lowest values from the remaining body of literature, it is likely that this value is conservative and would overestimate potential for adverse effects."*<br><br>The body of literature clearly demonstrates that the Murray three-generation reproductive study is fully supported by studies showing lower LOAELs. The Murray study is not conservative and does not overestimate the potential for adverse effects. Therefore, the following studies and language, as written, needs to be included the SRI, replacing the removed text.<br><br>*Latchoumycandane and Mathur (2002) conducted a sub-chronic study to determine whether treatment with vitamin E protected rat testes from TCDD-induced oxidative stress. Groups of male rats were administered an oral dose of 0, 1.0, 10, or 100 ng TCDD/kg-day for 45 days, while another group of animals was co-administered TCDD at the same doses, along with vitamin E at 20 mg/kg-day. The 1.0 ng TCDD dose is the same as lowest low dose used in the Murray three generation rat study. Testis, epididymis, seminal vesicle, and ventral prostate weights in the TCDD-treated groups decreased significantly ($p < 0.05$) and sperm production also decreased significantly ($p < 0.05$) in a dose related response when compared to controls. None of these changes were observed in the TCDD-exposed groups receiving vitamin E. A LOAEL of 1.0 ng/kg-day was found for reduced sperm and decreased reproductive organ weights ($p < 0.05$). A NOAEL could not be determined for this study.*<br><br>*Shi et al. (2007) administered pregnant rats oral doses of 0, 1, 5, 50, or 200 ng/kg TCDD on gestational days 14 and 21 and on post-natal days 7 and 14 for lactational exposure to pups. Ten female pups per treatment were selected and administered TCDD weekly at the same dose levels through their reproductive lifespan (approximately 11 months). The corresponding equivalent daily TCDD doses were 0, 0.14,* |

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| | | | | *0.71, 7.14, and 28.6 ng/kg-day. Serum estradiol concentrations were decreased at all time points across the estrous cycle in a dose-dependent manner with a statistically significant decrease (p < 0.05) in all but 0.14 ng/day group. TCDD exposure, however, did not affect ovarian follicles; responsiveness of the pituitary gland to gonadotropin-releasing hormone, or serum profiles of FSH, LH, or progesterone. A LOAEL for TCDD of 0.71 ng/kg-day for an 11-month exposure duration was identified in this study based on significantly (p < 0.05) decreased estradiol levels in offspring. The NOAEL for the study was found to be 0.14 ng/kg-day.*<br><br>In Section 4, two teratogenic studies are cited (Courtney et al, 1970 [listed in the references as Courtney and Moore, 1971]; and Couture et al., 1989) in support of the Sparschu gestational 10-day acute study. Courtney and Moore was also a 10-day a gestational exposure study and must be cited as a 10-day, short-term study. Based upon the previous discussion of the Sparschu study, the Courtney and Moore study has no relevance in determining LOAELs/NOAELs and RBCs for TCDD. The Couture study is based upon 2,3,4,7,8-PCDF, which has significantly lower toxicity (TEF=0.3) than 2,3,7,8-TCDD. As discussed by Sample et al. (1996) and Galbraith (2004) it must not be considered in TRV development or in selecting site RBCs. If AMEC/GP choses to maintain the citation, then the conclusions from both the Sample and Galbraith analyses will need to be included in a revised document. Regardless, both the Sample and Galbraith analyses need to be cited and discussed in the SRI.<br><br>Courtney, K. and J Moore. 1971. Teratology studies with 2,4,5-trichlorophenoxyacetic acid and 2,3,7,8-tetrachloro-dibenzo-p-dioxin. *Toxicol. Appl. Pharmacol*. 20: 396–403.<br><br>Couture, et al. 1989. Developmental Toxicity of 2,3,4,7,8-Pentachlorodibenzo furan in Fisher 344 Rat. *Fund. Appl. Toxicol*. 12: 358-366.<br><br>Latchoumycandane, C. and Mathur, P. Effects of vitamin E on reactive oxygen species-mediated 2,3,7,8-tetrachlorodibenzo-p-dioxin toxicity in rat testis, *Journal of Applied Toxicology*, 22, pg. 345-351, 2002.<br><br>Murray, et al., Three generation reproduction study off rats given 2,3,7,8- Tetrachlorodibenzo-p-dioxin (TCDD) in the diet, *Toxicology and Applied Pharmacology*, Vol. 50 (2), pgs. 241-252, 1979.<br><br>Sample, B.E., D.M. Opresko, and G.W. Suter. 1996. Toxicological benchmarks for wildlife: 1996 revision. Department of Energy, Oak Ridge, TN.<br><br>Sparschu, et al., Study of the teratogenicity of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in the rat, *Food and Cosmetic Tox.* 9(3), pg., 405-412, 1971.<br><br>Galbraith Environmental Services. 2004. Tittabawassee river floodplain screening-level ecological risk assessment: Polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans, Submitted to: Michigan department of environmental quality, Galbraith Environmental Sciences LLC, April 2004. http://www.michigan.gov/documents/deq/deq-whm-hwp-dow-TR-FloodplainReport_251817_7.PDF<br><br>EPA. 1987. 2,3,7,8-Tetrachlorodibenzo-p-dioxin, Health Advisory, Office of Drinking Water, March 31, 1987.<br><br>EPA. 1985. Health Assessment for Polychlorinated Dibenzo-p-dioxins, EPA/600/8-84/014F, September 1985.<br><br>EPA. 1995. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife: DDT, Mercury, 2,3,7,8-TCDD, PCBs. EPA-820-B-95-0083.<br><br>Appropriate discussion of Murray et al. and Sparschu et al. must be included in all sections where TRVs are considered. |

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| 75. | L6-49<br><br>L6-50<br><br>L6-72 | Appendix L, Section 6.4.4.5.3 & Figure L6-10<br><br>Appendix L, Section 6.4.4.5.4<br><br>Appendix L, Section 6.5.2.4 & Figure L6-12 | | The LOAEL TRV derived for birds (derived from an injected does of 140 ppt/d) killed more than half of the exposed birds in the cited study. Yet the TBERA derives an avian RBC range that reflects doses up to 500 times higher than the avian acute $LD_{50}$. The LOAEL TRV for mammals showed significant mortality at 100 ppt. Yet the TBERA derives a mammalian RBC range that reflects doses up to 750 times that exposure. These very large differences in RBCs reported from other sites, including the Tittabawassee River, and the literature need thorough explanation which takes into account the difficulties with TRV evaluation noted in previous comments. RBCs that indicate that exposed receptors will receive lethal doses cannot be used to define RBC useful for risk management. |
| 76. | L6-71 | Appendix L, Section 6.5.2.4 | | The section is titled, "Weight of Evidence for Carnivorous Birds and Mammals", but there were no carnivorous birds included in the TBERA. There was one carnivorous mammal, the red fox, but the fox is not mentioned in this section and the WOE results for the fox are not summarized. Additionally, the shrew (a vermivorous mammal) is discussed in this section. Revise the section to include the fox and delete the mentions of birds and shrews. |
| 77. | L7-1 | Appendix L, Section 7 | First paragraph | The TBERA risk summary states that unacceptable risk is not anticipated based on LOAEL-based risk estimates. However, according to EPA's ERAGS, the LOAEL-based risk estimates are by definition the contaminant concentrations at which adverse impacts are likely. The TBERA ignores the NOAEL-based risk estimates, but the NOAEL-based estimates should be primary endpoints used to assess risk, as noted in the comments above.<br><br>This section will also require revision to reflect the corrected HQ and RBC calculations discussed in the following comment, along with the corrected earthworm BSAFs, the appropriate TRVs for bioaccumulative compounds, and the revised RBCs. |
| 78. | L7-1 | Appendix L, Section 7, 1st paragraph | | The TBERA risk summary states that unacceptable risk is not anticipated based on LOAEL-based risk estimates. However, according to EPA's ERAGS, the LOAEL-based risk estimates are by definition the contaminant concentrations at which adverse impacts are likely. The TBERA ignores the NOAEL-based risk estimates, but the NOAEL-based estimates should be the primary endpoints used to assess risk. |
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